DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

525 8/20/97
RB 8/14/97

Certified/Return Receipt Requested

August 12, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Gerald A. Miller, Owner and
Chairman
Continental Laboratories, Inc.
1769 West Armitage
Chicago, IL 60622

Ref.# - 97-KAN-024

Dear Mr. Miller:

During an inspection of your firm known as Continental Laboratories, Inc., Madrid, Iowa, on June 10 to 18, 1997, our investigators determined that your firm manufactures sterile procedural kits for use in wound dressings, IV starters and tracheostomies. Procedural kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and conduct a formal medical device quality assurance program. No quality assurance audits have been performed since 1996, when device manufacturing was initiated.

2. Failure to conduct process validation of the [redacted] packaging machine, and calibration of the [redacted] Tension/Compression Tester which is used to test package seal strength.

3. Failure to maintain complete device history records of procedural kits and components to demonstrate that they are manufactured in accordance with the device master record. For example, a review of 23 device history records found no tests for seal strength on 14 lots; no lots tested for seal strength after sterilization; for all lots, no documented review of the sterilization cycle to ensure parameters were met; no

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CRP:ak

documentation in at least 8 device history records of the quantity of kits packaged.

4. Failure to investigate the failure of a device to meet performance specifications after a device has been released for distribution, and to make a written record of the investigation including conclusions and follow-up. For example, there are no records of failure investigations for lot no. 1394, IV Start Kit, which had a [redacted] defect rate in the package seals, and lot no. 1391, Wound Care Kit, which had 18 packages fail the seal integrity test.

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with Mr. David A. Bequeaith, President. A copy is enclosed for your information.

During the above inspection samples of your sterile medical devices were collected to test for seal integrity. Samples included Wound Care Tray with lot no. 1391, Trach Care Kit with lot no. 1400 and IV Start Kit with lot no. 1395. FDA analysis found all three samples to contain defective seals at a rate of at least [redacted] The sterility of these devices is questionable. You need to determine a course of action to assure the devices are not used.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in

regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: David A. Bequeaith, President
Continental Laboratories, Inc.
912 South State Street
Madrid, IA 50156